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MAR 23 2007

Docket No.: 2000.615 USD2

Application No. 10/698,230  
Amendment dated March 23, 2007  
Reply to Office Action of February 26, 2007

**REMARKS**

Applicants respectfully request entry of the above amendments and reconsideration of the restriction and election requirements and the rejections of the claims.

**Amendments**

As a result of the forgoing amendment, claim 24 (from which all other pending claims depend) has been amended to require that the highly purified diatomaceous earth has been leached to remove soluble impurities, has a total SiO<sub>2</sub> content of at least about 95% and a silica specific volume of greater than about 3.4. Support for this amendment can be found throughout the specification, including in the third full paragraph of page 8. Entry of this amendment after final is appropriate for at least two reasons. First, these limitations were argued in Applicant's last response, based on the language "highly purified diatomaceous earth" found in the claims and its definition found on page 8 of the specification. Accordingly, entry of this amendment does not raise any new issues. Secondly, entry of this amendment either places this application in condition for allowance or reduces the number of issues for appeal, because entry of this amendment overcomes the obviousness rejections presented.

**Continuing Traverse of Restriction and Election Requirements**

In the final Office Action of February 26, 2007, applicants' traverse of the earlier restriction and election requirements is acknowledged and discussed, but the restriction and election are maintained. See pages 2 thru 5 of the final Office Action. The undersigned attorney continues to strenuously contest the propriety of this restriction and election. As was pointed out in Applicants' responses of May 9, 2006 and November 17, 2006 and again in a telephone interview with Examiner Lukton on November 16, 2006, *no rationale for the restriction requirement has ever been placed on the record in this application*. There is no statement anywhere in the record why the USPTO considers Restriction Group I (drawn to a method for removing suspended particles from a protein solution, and wherein there is no requirement or suggestion that a cysteine thiol group be blocked) and Restriction Group II (drawn to the method for removing suspended particles from a protein solution including a further step of blocking a cysteine thiol group) are

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distinct inventions requiring restriction. Such a statement is an absolute requirement for a valid restriction requirement. See MPEP §809.02(a), where step (B) of establishing a species election requires the Examiner to "[p]rovide reasons why the species are independent or distinct." The repeated failure to present any such rationale leaves the appearance that the restriction requirement is entirely arbitrary and at the whim of the Examiner. The restriction requirement is improper and should be withdrawn.

In response to Applicants arguments about the propriety of the restriction, the Examiner makes the following statements in the final Office Action:

"The examiner will concede that it could be argued that the invention of claim 24 could be viewed as encompassing the invention of claim 33, and that a restriction (as opposed to election of a subgenus) might not be fully justified. But even if true, the point is largely moot, since there would have been nothing improper about requiring election of one of two subgenera, namely (i) a process in which cysteine sulfhydryls are blocked or (ii) a process in which cysteine sulfhydryls are not blocked. Thus even if the restriction (*per se*) were to be withdrawn at this particular point, the election of a subgenus would still be in force ... The issue of restriction, however, is now superceded [sic] by the issue of obviousness ... The restriction is maintained at the present time."

Applicants submit that the restriction is not moot, because Applicants' claims remain withdrawn and are not being examined. Furthermore, the argument that the Examiner can maintain an improper restriction because he might have made a different election requirement is nonsense. The restriction requirement is improper and must be withdrawn.

Applicants also restate their traverse of the species election requirement. As was stated in the Applicant's May 8, 2006 response, this species election requirement is improper, because *there is no stated reason for the species election*. This species election appears to be entirely at the whim of the Examiner and without any cause in US law or US Patent and Trademark Office procedure. Accordingly, this species requirement is improper and should be withdrawn.

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Furthermore, Examiner Lukton makes the following mysterious statement on page 2 of the February 26, 2007 final Office action on the subject of Applicants' arguments against restriction:

"Applicants have continued to traverse the restriction between Groups I (claims 24-32, 42-43) and II (claims 33-41). Applicants have argued that they can see no distinction between them."

No such Applicant or Attorney argument for a lack of distinction between Groups I and II appears on the record or was ever made. Applicants respectfully request that Examiner Lukton take more care not to attribute to Applicants or the undersigned attorney arguments that were not made (this has happened repeatedly in this application and in related divisional applications). Applicants further request that Examiner Lukton make a statement on the record showing clear support for the above characterization of Applicants' arguments or clearly withdrawing the statement. Although Applicants have repeatedly pointed out that the Examiner has failed to provide a proper restriction of the claims because the restriction fails to state any reason why Groups I and II are distinct, such statements are not equivalent to the argument the Examiner falsely attributes to Applicants.

#### Obviousness-type Double Patenting Rejections

Claim 33 stands [provisionally] rejected under the judicially-created doctrine of obviousness-type double patenting over both US 6,995,246 and co-pending application 10/873,801. Applicants respectfully traverse both of these rejections as being improper. Neither rejection provides any comparison of the different limitations of each set of claims or makes any statements as to why the differences in the claimed methods would have been obvious to one of skill in the art. Accordingly, both rejections are improper, because they fail to present a *prima facie* case of obviousness-type double patenting. Reconsideration and withdrawal of this rejection are respectfully requested.

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Claims 33-38 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rationale for the rejection is given as follows:

"The claims are dependent on a non-elected claim. In addition, the objective of merely "removing particles" is not consistent with the required process step, i.e., sulfitolysis of sulfhydryl groups. Some other, more suitable objective of the claimed method should be stated." See page 6 of the final Office Action.

Applicants respectfully request reconsideration and withdrawal of this rejection.

The fact that the claims depend from a non-elected claim does not make them indefinite. There is no uncertainty, whatsoever, as to which limitations are included in the elected claims. For instance, where elected claim 33 depends from non-elected claims 28, 26, 25 and 24, there is no uncertainty that all limitations of claims 24, 25, 26 and 28 are included in elected claim 33.

The fact that the preamble of the claim describes the method as "a method for removing suspended particles from a soluble protein solution" also does not make the claims indefinite. All of the instant claims require the step of "filtering the soluble protein solution through highly purified diatomaceous earth, thereby providing a clarified soluble protein solution." Accordingly, all the instant claims are a method for removing suspended particles from a soluble protein solution. The preamble is appropriate and this rejection should be withdrawn.

**Claims are Non-obvious**

Claims 33, 34 and 38 remain rejected under 35 U.S.C. §103 as being unpatentable over Hsu (US 6,008,328) in view of Hennen (US 6,468,534) or Colpan (US 6,274,371). Reconsideration and withdrawal of this rejection are respectfully requested. This obviousness rejection is improper because none of the references, taken individually or as a combined whole, teach or suggest the instant limitation that the filtration must take place through "highly purified" diatomaceous earth, wherein the highly purified diatomaceous earth has been leached to remove soluble impurities, has a

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total SiO<sub>2</sub> content of at least about 95% and a silica specific volume of greater than about 3.4. Although the Examiner argues that the needs of the marketplace would incite manufacturers and sellers of diatomaceous earth to provide the highest purity product possible, this is pure rhetoric, without any prior art substantiation, and furthermore ignores another pressure of the marketplace, maintaining a low cost of goods. In short, none of the cited prior art, or its combination, teach the use of highly purified diatomaceous earth, wherein the highly purified diatomaceous earth has been leached to remove soluble impurities, has a total SiO<sub>2</sub> content of at least about 95% and a silica specific volume of greater than about 3.4.

This rejection is further improper, because the instant claims all require a process "comprising the step of filtering the soluble protein solution through highly purified diatomaceous earth, thereby providing a clarified soluble protein solution". The clear meaning of this limitation (and particularly the word "thereby") is that it must be the filtration through diatomaceous earth that provides a clarified soluble protein solution, and not some other step. All the prior art cited against the instant claims teaches diatomaceous earth only as a "filter aid", and requires some other matrix for the actual filtration step. Accordingly, none of the prior art, taken singly or combined, teaches the instant limitation of a step of diatomaceous earth filtration that results in a clarified soluble protein solution. This rejection is improper and should be withdrawn.

Claims 33 - 38 remain rejected under 35 U.S.C. §103 as being unpatentable over Hsu (US 6,008,328) in view of Bobbitt (US 4,923,967) and further in view of Hennen (US 6,468,534) or Colpan (US 6,274,371). Reconsideration and withdrawal of this rejection are respectfully requested. This rejection is improper because none of the references, taken individually or as a combined whole, teach or suggest the instant limitation that the filtration must take place through "highly purified" diatomaceous earth, wherein the highly purified diatomaceous earth has been leached to remove soluble impurities, has a total SiO<sub>2</sub> content of at least about 95% and a silica specific volume of greater than about 3.4. Although the Examiner argues that the needs of the marketplace would incite manufacturers and sellers of diatomaceous earth to provide the highest purity product possible, this is pure rhetoric, without any prior art substantiation, and furthermore

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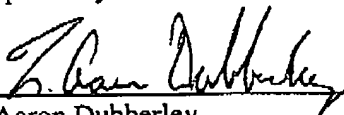
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ignores another pressure of the marketplace, maintaining a low cost of goods. In short, none of the cited prior art, or its combination, teach the use of highly purified diatomaceous earth, wherein the highly purified diatomaceous earth has been leached to remove soluble impurities, has a total SiO<sub>2</sub> content of at least about 95% and a silica specific volume of greater than about 3.4.

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Dated: March 23, 2007

Respectfully submitted,

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